DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 9, 2014

Visicu, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K141706
Trade/Device Name: Visicu, Inc. eCareCoordinator
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (Two)
Product Code: DRG
Dated: August 26, 2014
Received: August 28, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

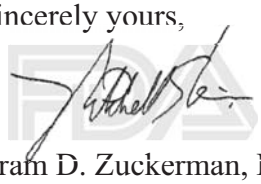
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141706

Device Name
eCareCoordinator

Indications for Use *(Describe)*
eCareCoordinator and its accessories are indicated for use by patients and by care teams for collecting and reviewing patient data from patients who are capable and willing to engage in use of this software, to transmit medical and non-medical information through integrated technologies.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TAB 6

510K SUMMARY

The Company's 510(k) Summary is provided on the following page.

{Please turn the page}

510(k) Summary

Submitter Chris Ferguson
Visicu, Inc.
217 E. Redwood Street, Suite 1900
Baltimore, MD 21202
Telephone: 410-276-1960
Fax: 410-276-1970

Date Prepared: July 14, 2014

Trade/Proprietary Name: eCareCoordinator (eCC)

Common Name: Telemedicine System

Classification Name: Transmitters And Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Predicate Device

M3810A Philips Telemonitoring System (PTS) (K103214)

M3810A Philips Telemonitoring System (PTS) (K041674)

Device Description

eCareCoordinator (eCC) is a software-only telemedicine system. eCareCoordinator (eCC) is a combination of technology and clinical programs designed to enable the support of patients in the home setting. eCC is intended to support the clinician with monitoring of remote patients. Clinicians use eCC to manage populations of ambulatory care patients, while keeping primary care physicians informed of patient status.

eCC is comprised of the following primary components:

- **eCareCoordinator (eCC)**: eCC is the platform supporting the Clinical User Interface. eCC is a cloud-based system, which is used to acquire patient data from home devices, as well as provide a population management triage dashboard to enable the clinician's team to prioritize and manage populations of patients.

- **eCareCompanion (eCP)**: eCP is a patient application element of eCareCoordinator used to engage patients in their own health. eCP is a mobile application which runs on an commercial off-the-shelf (COTS) Android tablet. Patients manually input measurements (including weight, blood pressure, pulse, blood glucose concentration, SpO2, temperature, prothrombin time (PT), coagulation ratio (INR), and transthoracic impedance) from measurement devices into the COTS tablet containing eCP. The COTS tablet wirelessly communicates with eCC to transmit the data stored by eCP to eCC.

Accessories

The eCC Clinical User Interface is able to receive data from Philips Telehealth Solutions (PTS) Telestations.

Intended Use

eCareCoordinator is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCareCoordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.

Indications for Use

eCareCoordinator and its accessories are indicated for use by patients and by care teams for collecting and reviewing patient data from patients who are capable and willing to engage in use of this software, to transmit medical and non-medical information through integrated technologies.

Comparison of Indications for Use

Although the indications for use for the eCC and the PTS (K103214 / K041674) are not written identically, the stated indications for use are considered to be substantially equivalent, in that both devices are intended to be used in the data collection (aggregation)of patient measured physiological parameters (i.e., weight, blood pressure, etc.); both devices are intended to provide clinical information to a remote care team (i.e., clinical professional), both devices are not intended to be a substitute for professional judgment, and both devices do not send any real time alarms to the end user.

Technological Characteristics

Clinical User Interface

Both eCC and PTS feature a clinical user interface (eCC Clinical User Interface and M3817B server with M3811B Clinical Review Software, for eCC and PTS, respectively) that allows clinical users to review patient measurement and survey data.

Patient User Interface

Both eCC and PTS feature a patient user interface (eCP and the PTS telestation, for eCC and PTS, respectively) that allows patients to respond to surveys or enter data from measurement devices. As compared to the predicate PTS, eCC allows for substantially equivalent means of data entry by allowing the patient to manually enter data read from measurement devices.

Surveys

Both eCC and PTS give clinical users the option of sending surveys to patients in order to determine additional information about their health status. Patient surveys are sets of questions, educational materials, quizzes, or assessments that are sent to at-home users via the eCP app or the PTS telestation

Protocols

Protocols are an option in eCC that allows the creation of patient tasks and intervention rules which trigger a flag. Both eCC and PTS present flags in the clinical application as a notification to clinical users that an item requires attention. In both eCC and PTS, flags are triggered by out-of-range patient data or missed patient data. Clinical users review flags and may take action, including review of individual patient treatment plans, as necessary.

Performance Data

Bench tests were executed to verify and validate eCC. Verification testing consisted of verification of the system-level requirements and verification of the sub-system level requirements. Validation testing consisted of formative usability testing and summative usability testing. The verification and validation test results confirm that eCC performs as intended.

Substantial Equivalence

Table 1 below summarizes the comparison of eCC and its predicate device, PTS. eCC and PTS have the same intended use and similar indications, technological characteristics and principles of operation. As discussed above, the technological differences do not change the intended use or present any new issues of safety or effectiveness. Software verification and validation testing, in addition to usability testing conducted to validate the user interface and labeling, demonstrate that the proposed device performs as intended. Thus, eCC is substantially equivalent to PTS.

Table 1. Substantial Equivalence Chart.

	eCareCoordinator (eCC)	**M3810A Philips Telemonitoring System (PTS) (K103214)**	**M3810A Philips Telemonitoring System (PTS) (K041674)**	**Comparison**
Intended Use	Telemedicine system	Telemedicine system	Telemedicine system	Same
Indications for Use	eCareCoordinator and its accessories are indicated for use by patients and by care teams for collecting and reviewing patient data from patients who are capable and willing to	The M38IOA Philips TeleMonitoring System with eDevice BridgeD130 is indicated for patients at home, who are capable and willing to self	The M3810A is indicated for patients at home, who are capable and willing to self administrate this device, upon prescription of their healthcare provider, to	Substantially equivalent to K103214 and K041674

	engage in use of this software, to transmit medical and non-medical information through integrated technologies.	administrate this device, upon the prescription of their healthcare provider, to collect and transmit medical information such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone lines or cellular connectivity to the healthcare provider. The device may be used for the management of congestive heart failure, hypertension, ischemic heart disease, weight management, cardiovascular risk management, post cardiovascular surgery, post myocardial infarction, and other post cardiac	collect and transmit medical information, such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone time to the healthcare provider. The device does not send any real-time alarms. Clinical judgment and experiences are required to check and interpret the information delivered.	

		events. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.		
User Population	Home users and healthcare providers	Home users and healthcare providers	Home users and healthcare providers	Same
Measuring devices and functionality	Measurements are entered manually into eCP.	Measurements are either entered manually or measurement devices wirelessly communicate with the PTS telestation.	Measurements are either entered manually or measurement devices wirelessly communicate with the PTS telestation.	Substantially equivalent to K103214 and K041674
Alarm functionality	None	None	None	Same
Connectivity from patient home to clinical server	Wireless connectivity	Wireless connectivity or telephone lines	Wireless connectivity or telephone lines	Substantially equivalent to K103214 and K041674
Patient data review	Clinical users can review patient measurement data and survey data	Clinical users can review patient measurement data and survey data	Clinical users can review patient measurement data and survey data	Same
Flags/Intervention Rules	The clinical user interface features flags as a notification to clinical users that an item requires attention. Flags are triggered by intervention rules that determine that patient data is out-	The clinical user interface features flags as a notification to clinical users that an item requires attention. Flags are triggered by intervention rules that determine	The clinical user interface features flags as a notification to clinical users that an item requires attention. Flags are triggered by intervention rules that determine	Substantially equivalent to K103214 and K041674

	of-range or that there is missed patient data, or that a survey score is out-of-range. Clinical users review flags and may take action, as necessary. Intervention rules can also send a survey task to the patient, send a measurement task to the patient, or create a clinician task.	that patient data is out-of-range or that there is missed patient data, or that a survey score is out-of-range. Clinical users review flags and may take action, as necessary. Intervention rules can also send a survey task to the patient.	that patient data is out-of-range or that there is missed patient data, or that a survey score is out-of-range. Clinical users review flags and may take action, as necessary. Intervention rules can also send a survey task to the patient.	
Surveys	Clinical users have option to send surveys to patients	Clinical users have option to send surveys to patients	Clinical users have option to send surveys to patients	Same
Protocols	Clinical users have option of assigning protocols (which are a convenient way to schedule patient tasks to take surveys and measurements, as well as define intervention rules) to patients.	Clinical users have option of assigning profiles (which are a convenient way to schedule patient tasks to take surveys as well as define intervention rules) to patients. Clinical users separately schedule patient tasks to take measurements and define intervention rules.	Clinical users have option of assigning profiles (which are a convenient way to schedule patient tasks to take surveys as well as define intervention rules) to patients. Clinical users separately schedule patient tasks to take measurements and define intervention rules.	Substantially equivalent to K103214 and K041674